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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,753	10/09/2001	Alan J. Schroit	UTSC:594USD1/MBW	8205

7590 12/16/2002

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,753	SCHROIT, ALAN J.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-27 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 10 (*in part*) , 12 and 26-27 (*in part*) as solely drawn to a method for inhibiting cancer cell growth or killing cancer cells or generating an immune response comprising administering an a composition comprising a **lipid/polypeptide** conjugate, classified in class 424, subclass 193.1.

II. Claims 10-11, (*in part*) and Claim 26 (*in part*) as solely drawn to a method for treating cancer comprising contacting a subject with a **lipid**, classified in class 424, subclass 184.1.

III. Claims 13 and 15 (*in part*) and Claims 18-21 as solely drawn to an antibody that binds to a **lipid** (phosphatidylserine), including linked antibodies, and monoclonals thereof, and methods of generating such antibodies, classified in class 530, subclasses 386, 388.1.

IV. Claims 13 (*in part*) 14, 15 (*in part*), and 16-21 as solely drawn to an antibody that specifically binds to a phosphatidylserine/polypeptide conjugate or a

phosphatidylcholine/polypeptide conjugate, including linked antibodies, and monoclonals thereof, and methods of generating such antibodies, classified in class 530, subclass 386, 388.1.

V. Claim 22 (*in part*) as solely drawn to a method of detecting a phosphatidylserine lipid, classified in class 435, subclass 4.

VI. Claim 22 (*in part*) as solely drawn to a method of detecting a phosphatidylserine/polypeptide conjugate or a phosphatidylcholine/polypeptide conjugate, classified in class 435, subclass 7.1.

VII. Claims 23 (*in part*) and Claims 24-25, as solely drawn to an immunodetection kit comprising an antibody that specifically binds to phosphatidylserine, classified in class 435, subclass 810.

VIII. Claims 23 (*in part*) and Claims 24-25, as solely drawn to an immunodetection kit comprising an antibody that specifically binds to a phosphatidylserine/polypeptide conjugate or a phosphatidylcholine/polypeptide conjugate, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups III-IV, VII-VIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups I-II, V-VI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Groups III (and VII) and the methods of Groups V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group IV (and VIII) and the methods of Groups VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Groups III-IV, (and VII-VIII) and the methods of Groups I-II are not at all related because the products of Groups III-IV, (and VII-VIII) are not used in any of the methods of Groups I-II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Elections:

Group I (Claim 2) is generic to a plurality of disclosed patentably distinct species comprising the following distinct cancer cell types:

(a) lymphoid cancer cells, (b) renal cancer cells, or (c) bladder cancer cells

The above species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Additionally, Group I (Claims 7-8, and 27) is generic to a plurality of disclosed patentably distinct species comprising the following:

a) BSA

b) KLH

c) BGG

d) diphtheria toxin

e) β2-glycoproetin I

Group IV (Claims 14, 16-17) is generic to a plurality of disclosed patentably distinct species comprising the following:

a) phosphatidylserine/BSA

b) phosphatidylserine/KLH

c) phosphatidylserine/BGG

d) phosphatidylserine/β2-glycoprotein I

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
December 13, 2002